Human Growth Hormone Serostim (Serono) Somatropin (rDNA Origin) Questionnaire

Prior Authorization Request Form (PA/RF) must be completed and signed by a physician experienced in the diagnosis and management of acquired immune deficiency syndrome (AIDS)

Please enclose separate sheets for answers requiring more space than is provided on this form.

Recipient Name_____ Recipient Medicaid Number_____

Diagnosis

1. Does this patient have human immune deficiency virus (HIV) with serum antibodies to HIV? YES ___ NO ___
2. Is the patient at least 18 years of age? (must be at least 18 years of age to qualify) YES ___ NO ___
3. If the patient is a female, is she pregnant or lactating? YES ___ NO ___

Current Medical Condition of the Patient

4. Does the patient have any signs or symptoms of AIDS or associated illnesses? YES ___ NO ___
5. Does the patient have an untreated or suspected serious systemic infection or persistent fever greater than 101 degrees Fahrenheit? YES ___ NO ___
6. Does the patient have an active malignancy other than Kaposi's Sarcoma? YES ___ NO ___
7. Is the patient receiving antiretroviral therapy concurrently with human growth hormone? The patient must be on an antiretroviral therapy that is approved or available under a treatment IND, and agree to continue antiretroviral medication while taking Serostim. Individuals on 3TC must also be receiving AZT. YES ___ NO ___
8. Individuals with documented hypogonadism may be on replacement therapy with gonadal steroids. Is this the case with this patient? YES ___ NO ___

Evidence of Wasting Syndrome

9. Patient's height _____
10. Patient's usual weight prior to diagnosis of HIV _____
11. Patient's current weight _____
12. Does the patient have an unintentional weight loss of at least 10% from baseline premorbid weight? YES ___ NO ___
13. Does the patient have an obstruction or malabsorption to the degree to account for the weight loss? YES ___ NO ___

All of the Following Procedures Are to Be Tried Before Beginning a Course of Therapy with Human Growth Hormone

14. The patient must be receiving at least 100% of estimated caloric requirement on his/her current regimen. Please include the type and use of enteral nutrition product(s) used, with weight status before and after use, how long the course of treatment was used, and why, or if the treatment was discontinued. (Individuals receiving assisted enteral or parenteral nutrition must be weight stable for at least two months or have persistent weight loss despite such interventions, and must still meet the eligibility of criterion # 12.)

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15. A course of generally accepted therapy with megesterol acetate and/or dronabinol for appetite stimulation must have been tried. Please describe the program of treatment, and how long the treatment was used, and why the treatment was discontinued. _____

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16. A course of therapy using dihydrotestosterone (this has Orphan Drug Product Designation for the treatment of weight loss in HIV-positive and AIDS patients) must be tried for suitable patients. Please describe the physician's program of treatment and how long the course of treatment was, the results of the treatment, and why the treatment was discontinued. _____

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17. A course of therapy with a protease inhibitor, either alone or concurrently with one or more nucleosides must have been tried. Please describe the program of treatment, how long the course of therapy was, and why the treatment was discontinued. (This course of therapy should last at least 24 weeks before the planned initiation of Serostim.) _____

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Manufacturer's Treatment Guidelines

18. Upon completion of two weeks' treatment, please assess the patient's weight status. If the patient has no weight loss during the two-week trial, continue for an additional 10 weeks' therapy.

    Initial weight _____
    Weight after two weeks of therapy _____

19. Upon completion of two weeks treatment in cases where patient continues to lose weight, please rule out underlying causes for weight loss. If the patient is not experiencing additional condition(s) contributing to weight loss, continue for an additional four weeks' therapy. Continued weight loss precludes additional use beyond the six weeks. If patient's weight increases during the additional four-week therapy, continue for an additional six weeks' therapy.

    Weight after six weeks of therapy _____
    Weight after 12 weeks of therapy _____

20. Efficacy of this drug beyond 12 weeks has not been established. Wisconsin Medicaid may approve initial therapy only to a maximum of 12 weeks.

Physician's Signature _____ Date_____